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March 30, 2007

TELECOPY

TO :	**OFFICE OF PETITIONS**
FIRM :	**UNITED STATES PATENT AND TRADEMARK OFFICE**
FAX :	571-273-8300
Y/FILE:	10/582,082
FROM :	**JULIE GAUVREAU**
TELEPHONE :	**514-397-4374**
O/FILE :	**765/14304.9**
TOTAL PAGES :	7 (including this one)

Dear Sirs:

Upon verification of the Image File Wrapper of application no. 10/582,082, we noticed that our Protest under 37 CFR §1.291 filed on February 21, 2007 (a copy of our stamped postcard is enclosed) had not been entered.

We submit once again a copy of the Protest. A complete copy of all documents will be sent to the USPTO in the next few days.

Sincerely,

Julie Gauvreau

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Our File:	14304.9
Applicant:	Katsura Funayama et al.
International Publication Number:	WO 2005/056034
International Filing Number:	PCT/JP2004/0018369
International Filing Date:	9 December 2004
Title:	ALGA EXTRACT AND LIPASE INHIBITOR CONTAINING THE SAME
Customer number:	25545
Confirmation number:	N/A

****

February 21, 2007

PROTEST UNDER 37 CFR § 1.291

Attention: Office of Petitions
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
U.S.A.

Sir :

It is submitted that the present is the first protest submitted in the application by the real party in interest so that 37 CFR 1.291(e) does not apply.

The following presents arguments showing that the claims on file for the subject patent application are not patentable.

The subject claims relate to *Ascophyllum nodosum* extracts, as well as to compositions containing such extracts, for use as inhibitors of lipase and in methods for lowering plasma triglyceride and for treating obesity or hyperlipidemia.

2. CITABLE PRIOR ART

Barwell *et al* (1989)

Citable prior art under 35 U.S.C. § 102(b)

Published in 1989, before the filing of the priority claimed for the subject patent application, December 10, 2003.

This reference discloses an extract of *Ascophyllum nodosum* which inhibits lipase (see Tables 1, 2 and 3 for instance). The effect on such digestive enzymes suggested potential use of the extract in modulating mammalian digestion (see for instance p. 322, right column, par. 2). Polyphenols were isolated from the extracts and identified as lipase inhibitors (see for instance P. 322, left column, par. 1).

Furthermore, Barwell *et al* teaches that the extracts that it discloses may be used as feed-stuffs for animal or human health foods (see p. 322, right column, par. 2).

Hadvary *et al.* (1988); Carrière *et al.* (2001); Xenical prescribing information (revised January 2005)

Citable prior art under 35 U.S.C. § 102(b) or 102(a)

Published in 1988 and 2001, before the filing of the priority claimed for the subject patent application, on December 10, 2003. Cited references published after this date (i.e., in 2005) are provided in support of prior art published before this date.

Hadvary *et al.* discloses that tetrahydrolipstatin specifically inhibits pancreatic lipase from several species *in vitro*, including human (see Fig. 1 for instance).

Carrière *et al.* discloses that tetrahydrolipstatin inhibits human pancreatic lipase (HPL) and human gastric lipase (HGL) *in vivo* in healthy human subjects (see Tables 2 and 3, and Fig. 2). This coincides with a significant lowering of gastric lipolysis (see Table 4), which contributes in turn to an increase in fat excretion after ingestion of a liquid meal *in vivo* (see Table 6). This reference thus generally discloses that this ant-lipase agent is an anti-obesity drug (see abstract for instance).

The Xenical (Orlistat™) prescribing information provides clinical pharmacological information regarding tetrahydrolipstatin, as an inhibitor of gastric and pancreatic lipases. Tetrahydrolipstatin administration has been shown to contribute to mean weight loss and

reduction of obesity risk factors, in the treatment of obesity in humans (see Tables 1-4 and Fig. 1 for instance). Tetrahydrolipstatin administration also reduced plasma cholesterol and triglyceride following 1-year treatment as compared to a placebo control (see Table 2). Xenical was approved for use as a treatment of obesity in humans by the FDA on April 23, 1999, well before the filing of the priority claimed for the subject patent application, on December 10, 2003.

Lamela *et al.* (1989)

Citable prior art under 35 U.S.C. § 102(b)

Published November 1989, before the filing of the priority claimed for the subject patent application, on December 10, 2003.

This reference discloses algal extracts from *Laminaria ochroleuca*, *Saccorhiza polyschides* and *Fucus vesiculosus*. Oral administration of *L. ochroleuca* extracts caused a significant reduction in serum triglyceride levels in normal rabbits (see p. 39, lines 19-26 and p.40, Table 2).

This reference also discloses the therapeutic value of preparations extracted from several species of algae, as treatments against elevated blood cholesterol and obesity (see p. 35, Introduction, lines 1-10).

Ohta *et al.* (2002) and Han *et al.* (2003)

Citable prior art under 35 U.S.C. § 102(b) or 102(a)

Published in 2002 and on December 5, 2003, respectively, before the filing of the priority claimed for the subject patent application, on December 10, 2003.

These references disclose extracts from dietary plant and algal sources with anti-obesity effects *in vivo*.

3. ARGUMENT

A. NOVELTY

It is submitted that Barwell *et al.* anticipates claims 1 to 3, 7 and 10, in that it explicitly discloses an *Ascophyllum nodosum* extract and purified fractions thereof which inhibit several digestive enzymes, including lipase (see Tables 1-3). Barwell *et al* also teaches that the extracts that it discloses may be used as feed-stuffs for animal or human health foods (see p. 322, right column, par. 2).

B. INVENTIVE STEP

Plasma Triglyceride-Lowering Agent and Methods of Treatment of Obesity and Hyperlipemia

It is submitted that a person of ordinary skill in the art would have been led to combine the teachings of Barwell *et al.* with those of the other above-cited references to achieve the plasma triglyceride-lowering agent and methods of treatment of claims 4-6,8-9 and 11-12.

Barwell *et al.* teaches that *Ascophyllum nodosum* extracts display a significant inhibitory activity towards lipase, with potential applications in modulating mammalian digestion.

The following references teach and/or suggest that extracts from a variety of dietary plant and algal sources displaying inhibitory activity against lipase alter fat utilization in mammals and may be used to prevent or treat obesity, hyperlipemia and elevated plasma triglycerides.

Lamela *et al.* teaches the therapeutic value of extracts from several species of algae as treatments against elevated blood cholesterol, elevated plasma triglycerides levels and obesity (see p. 35, Introduction, lines 1-10 (obesity, plasma triglycerides/ hyperlipemia); page 37, lines 36-40 and table 2, page 40 (plasma triglycerides/ hyperlipemia).

Ohta *et al.* (2002) disclose a 70% polysaccharide-containing extract from the brown alga Ezoishige (*Pelvetia babingtonii* de Toni) with the capacity to suppress the postprandial elevation in blood glucose after its oral administration to rats (see Fig. 2), suggesting a

potential role for extracts from brown algae as dietary treatments against obesity (see p.1554, left column, lines 10-14).

The references Hadvary *et al.* (1988); Carrière *et al.* (2001) and Xenical prescribing information (revised January 2005), together, provide *in vitro* and *in vivo* evidence for the capacity of tetrahydrolipstatin, a gastric and pancreatic lipase inhibitor, to reduce intestinal fat absorption and plasma triglycerides and treat obesity in humans.

From these combined teachings, a person skilled in the art would expect that *Ascophyllum nodosum* extracts, which are known to have inhibitory activity against lipase, will have therapeutic value against elevated plasma triglyceride, hyperlipemia and obesity in mammals. Accordingly, these teachings render the subject matter of claims 4-6, 8-9 and 11-12 obvious.

Notification has been served on the applicant's Attorney, Iwatani Patent Office, on February 19, 2007 by FedEx, Tracking Number 8590 1433 0940. For your convenience, a copy of the Way Bill is attached.

Authorization is hereby given to charge Deposit Account no. 07-1742 for any deficiencies or overages in connection with this response.

Respectfully submitted,

GOUDREAU GAGE DUBUC

by:_____
Julie Gauvreau
Registration No. 52,532

Julie Gauvreau
GOUDREAU GAGE DUBUC
2000 McGill College, Suite 2200
Montreal, Quebec, Canada H3A 3H3
Phone: (514) 397-4374
E-mail: *jgauvreau@ggd.com*

PROPERTY OF: DOWELL & DOWELL, P. C., Suite 406, 2111 Eisenhower Ave., Alexandria, VA 22314, Telephone (703) 415-2555

Katsura Funayama et al., WO 2005/056034, PCT/JP2004/0018369 12/9/04, ALGA EXTRACT AND LIPASE INHIBITOR CONTAINING THE SAME CUST NO. 25545 OUR REF.: 14304.9

THE U.S. PATENT AND TRADEMARK OFFICE STAMP INDICATES DATE OF FILING OF THE FOLLOWING MARKED DOCUMENTS

Protest under 37 CFR § 1.291
Copy of FedEx airbill
copy of Canadian Patent Application 2548899
copy of citable prior art references